



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0081]

Draft Guidance on Investigational New Drug Applications for Positron Emission Tomography Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled “Investigational New Drug Applications for Positron Emission Tomography (PET) Drugs.” The draft guidance is intended to assist manufacturers of PET drugs in submitting investigational new drug applications (INDs).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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Silver Spring, MD 20993,
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SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Investigational New Drug Applications for Positron Emission Tomography (PET) drugs.” The draft guidance summarizes the IND process for PET drugs, makes recommendations for how to submit an IND, provides advice on expanded access options for investigational PET drugs, and describes the process for requesting permission to charge for an investigational PET drug.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency’s current thinking on the submission of INDs for PET drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative

approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). INDs and requests to charge for a drug under an IND are submitted to FDA under part 312 (21 CFR part 312). NDAs and ANDAs are submitted to FDA under §§ 314.50 and 314.94 (21 CFR 314.50 and 3.14.94). The collections of information in part 312 and in §§ 314.50 and 314.94 have been approved under OMB control numbers 0910-0014, 0910-0653, 0910-0651, and 0910-0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>.

Dated: February 8, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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